

**GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE**

**LOK SABHA
UNSTARRED QUESTION NO. 3708
TO BE ANSWERED ON 24TH MARCH, 2017**

PATHOLOGICAL LABORATORIES

**3708. SHRI DILIPKUMAR MANSUKHLAL GANDHI:
SHRI DEVJI M. PATEL:**

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

- (a) whether there are no guidelines for the functioning of private laboratory in the country;
- (b) if so, the reasons therefor;
- (c) whether laboratories can be easily set up operated anywhere as licence is not required and if so, the details thereof;
- (d) whether such laboratories have no uniform policy and charge arbitrarily for the same test and if so, the details thereof and if not, the reasons therefor along with the steps taken by the Government to check it; and
- (e) whether the Government is formulating any scheme to monitor private laboratories in the country and if so, the details thereof and if not, the reasons therefor?

ANSWER

**THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(SMT. ANUPRIYA PATEL)**

(a) to (d): Health is a State subject and regulation of private pathological laboratories falls within the remit of State Governments. The Government of India has, however, enacted the Clinical Establishments (Registration and Regulation) Act, 2010 and notified Clinical Establishments (Central Government) Rules, 2012 for registration and regulation of Clinical Establishments, including Pathological Laboratories. The Act is currently applicable in ten States and all Union Territories except Delhi. In the State /UTs where the said Act is in force, the clinical establishments are required to meet the norms such as minimum standards of facilities and services, minimum requirement of personnel, maintenance of records and reports and displaying of rates at a conspicuous place. The clinical establishments are also required to follow Standard Treatment Guidelines issued by the Central/State Governments and charge rates for each type of procedure and service within the range of rates determined from time to time. The National Council for Clinical Establishments has approved a standard list of medical procedures and a standard template for costing medical procedures and shared the same with the States and Union Territories. Further action lies within the purview of the State/UT Governments.

(e): In view of the Clinical Establishments Act, 2010 having been enacted, no further action is required to be taken by the Central Government.